## REMARKS

Claims 1, 4 – 6, 8 – 10, 13 and 31 are currently pending. Claims 1, 4 – 6, 8 – 10, 13 and 31 have been rejected.

Reconsideration is respectfully requested.

### *Claim Rejections - 35 USC § 112 & 35 USC § 101*

Rejection of Claim 5 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claim 5 under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, it is the Examiner's view that "[a] single claim which claims both an apparatus (a stent having a plasma-polymerized polymer film layer) and the method steps of making the apparatus (wherein the plasma-polymerized polymer film is formed by exposing the stent to an acrylic acid plasma) is indefinite under 35 U.S.C. 112, second paragraph."

Rejection of Claim 5 under 35 U.S.C. § 101

The Examiner has also rejected claim 5 under 35 U.S.C. § 101. The Examiner has concluded that the claim is not statutory under 35 U.S.C. § 101 "based on the theory that the claim is directed to neither a 'process' nor a 'machine,' but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101, which is drafted so as to set forth the statutory classes of invention in the alternative only." The Examiner has cited MPEP § 2173.05(p) to support this conclusion.

Applicants' Response

Applicants traverse both the 35 U.S.C. § 112, second paragraph and the 35 U.S.C. § 101 rejections of claim 5.

The Manual of Patent Examining Procedure (MPEP), 8th Edition, § 2173.05(p)(I) notes "[a] product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper." However, "[a] single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph," and "such claims may also be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a 'process' nor a 'machine,'. . . ." MPEP § 2173.05(p)(II) (citations omitted).

Claim 5 recites "[t]he stent of Claim 1, wherein the plasma-polymerized polymer film layer is formed by exposing the stent to an acrylic acid plasma," and claim 1 recites "[a] stent comprising . . . a plasma-polymerized polymer film layer deposited over the stent body surface . . . ." Claim 5 is not directed to an apparatus and a method of using the apparatus, but a product, and the process by which an element of the product is made. Thus, claim 5 is a proper product-by-process claim.

Applicants respectfully request the withdrawal of both the 35 U.S.C. § 101 and the 35 U.S.C. § 112 rejections of claim 5.

Additionally, applicants would like to point out that the claim 5 has remained substantially unchanged since amendment submitted in the Response of September 24, 2007 to the Office Action of April 25, 2007. Furthermore, claim 5 currently recites "[t]he stent of Claim 1, wherein the plasma-polymerized polymer film layer is formed by exposing the stent to an acrylic acid plasma," and claim 5 as filed recited "[t]he stent of claim 3, wherein the polymer is formed by exposing the stent to an acrylic acid plasma." As MPEP § 706 states "[t]he goal of examination is to clearly articulate any rejection early in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity," Applicants ask why the Examiner has not made these rejections until the present Office Action?

***Claim Rejections - 35 USC § 103***

The Examiner has rejected claims 1, 4 – 6, 8 – 10 , 13 and 31 under 35 U.S.C § 103(a) as being unpatentable over Taylor et al., United States Patent Application No. 6,083,257 (Taylor), Ecer et al., United States Patent Application No. 4,486,247 (Ecer), Narayanan et al. United States Patent Application No. 5,336,518 (Narayanan) and Kraus United States Patent Application No. 6,712,816 (Kraus).

The Examiner's Position

The Examiner has stated that Taylor discloses a metallic stent, in particular, a stent body of stainless steel, that is coated with a polymer coating, the polymer coating being in intimate contact with the tissue contacting surface of the stent.

The Examiner admits that Taylor does not disclose that the stent body has a carbon deposit. For the carbon deposits, the Examiner has cited Ecer. According to the Examiner, Ecer discloses "a stainless steel base material being modified by having carbon implanted within the surface of the stainless steel base material at a depth from about 300 to about 2500 angstroms, or of about 300 to about 1000 angstroms below the steel surface." Citing column 1, lines 14 – 18 of Ecer, the Examiner further contends that Ecer discloses "carbon is a known material for increasing the hardness of steel." The Examiner also states that "[i]t is well known in the art that stainless steels having improved hardness yield stents having increased tensile strength, stiffness, and resistance to radial compression, thus improving the performance of the stent within, for example, a pulsating lumen." Based upon the above, the Examiner has concluded that "it would have been obvious to one having ordinary skill in the art . . . to provide Taylor's stainless steel stent body with a carbon deposit as taught by Ecer in order to provide the stent with the advantages described above."

The Examiner further admits that the combination of Taylor as modified by Ecer fail to disclose "the polymer film layer is 'chemically' bonded to the carbon deposit." To cure this deficiency, the Examiner has cited Kraus, which in the Examiner's view teaches a polymer coated metallic stent, and "the polymer may be applied to the metallic stent by chemical vapor deposition, thus chemically bonding the polymer film to the metallic stent." Then, the Examiner concludes that one of skill in the art would have known to apply the known technique of Kraus to the metallic stent of Taylor as modified by Ecer to yield "predicable results and resulted in an improved system." According to the Examiner, the improved system would have been "a metallic stent with a carbon deposit having a polymer film chemically bonded thereto (i.e., to the stent including materials within the stent body such as the carbon deposit), thus reducing the risk of the film inadvertently coming off of the stent during handling and/or deployment."

The Examiner also admits that Taylor does not disclose that the polymer coating is plasma polymerized. Narayanan is thus cited for the alleged disclosure of a metallic stent and a polymer coating that may include bioactive agents. According to the Examiner, the coatings of Narayanan are "plasma polymerized films, such as HFBMA (which is an acrylate), to enhance metallic surfaces with permanent improved biocompatibility," and these plasma polymerized polymer films provide "a stronger bond with the bioactive agents, since covalent linkages are formed between the film and the Agents." According to the Examiner, one of skill in the art

would have added a bioactive agent to the coating of Taylor to "to enhance treatment and promote healing at the treatment site," and would have "utilize[d] a plasma polymerized polymer film in Taylor's invention as taught by Narayanan in order to provide the advantages described above."

With respect to the dependent claims, the Examiner also points to other portions of Narayanan as disclosing the elements of claims 4 and 6. Claim 5 has been treated as a product-by-process claim by the Examiner, and thus, it is obvious as "the product disclosed by Taylor as modified by Ecer, Kraus, and Narayanan would be the same" as Applicants' claim 5, "especially since both applicant's product and the prior art product have the same final structure of a metallic stent having a plasma-polymerized polymer film layer."

Applicants' Response

Applicants traverse the 35 U.S.C § 103(a) rejection as the Examiner has not established a *prima facie* case of obviousness for the following reasons:

(1) One of skill in the art would not have looked to Ecer as Ecer is non-analogous art

(2) If one of skill in the art had looked at Ecer, one would not have combined Taylor and Ecer as the Examiner has proposed

(3) If one had combined Ecer, Taylor, Kraus and Narayanan as the Examiner has proposed, an element, "the plasma-polymerized film layer is chemically bonded to the carbon deposit," is not present in the combination

(4) The Examiner has combined the references in an inconsistent manner

(5) The Examiner is using hindsight

(1) One of skill in the Art would not have looked to Ecer – Ecer is non-analogous art

Ecer is non-analogous art. As noted in MPEP § 2141.01, "to rely on a reference under 35 U.S.C. § 103, it must be analogous prior art." Ecer is directed to "steels having high wear resistance and low friction surfaces" and methods for producing such steels. Ecer provides that exemplary uses for such steels are "machines having components, each having surfaces . . . which are in sliding, lubricated contact with each other under a load . . . " (Ecer, column 3, lines 41 – 44 ). In the "Background" section of the patent, Ecer also discloses the following at column 1, lines 11 – 18:

> In the past, the wear resistance of steel surfaces has been improved by subjecting the steel to a high temperature process in which a wear resistant coating is bonded to the surface or an element such as, carbon and/or nitrogen, is thermally diffused into the steel surface to locally increase the hardness of the steel itself in a relatively wide layer extending inwardly from the steel surface.

As noted above, Ecer is directed to wear and abrasion resistance of metallic parts as evidenced by the title of the invention, "Wear resistant steel articles with carbon, oxygen and nitrogen implanted in the surface thereof," with the one reference to increasing the local hardness of steel by thermally diffusing carbon into the surface.

The Examiner has then taken the one statement in Ecer as the rationale for turning to Ecer. However, MPEP § 2141.02 states "[a] prior art reference must be considered in its entirety, i.e., as a whole, . . . " . *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)." The Examiner has taken the one statement out of context. When viewed as a whole, Ecer is clearly not in the same art as Applicants' claimed invention, that is, implantable medical devices. Further, Ecer does not address the same problem as Applicants' claims. Ecer addresses the problem of friction and wear resistance, which is in contrast to the problem that Applicants' invention addresses, the adherence of a polymeric layer to a metal substrate of an implantable medical device. When viewed as a whole, one of skill in the art would not have looked to Ecer as Ecer is directed to the issue of wear and abrasion resistance and is not in the field of medical devices.

(2) One of Skill in the Art would not have combined Taylor and Ecer

In contrast to her earlier position that one would have modified Taylor to improve wear resistance as taught by Ecer, the Examiner has now taken the position that one would have modified the metallic stent of Taylor using the method of Ecer to improve the mechanical properties, specifically the tensile strength, stiffness, and resistance to radial compression, of a stent. The Examiner has reached this conclusion based upon one statement in the background section of Ecer, that is ". . . an element such as, carbon and/or nitrogen, is thermally diffused into the steel surface to locally increase the hardness of the steel itself in a relatively wide layer extending inwardly from the steel surface" (column 1, lines 14 – 18) (emphasis added).

It is Applicants' position that one of skill in the art who was looking to solve the problem of increasing the tensile strength, stiffness, and resistance to radial compression, of a stent, and in

particular, a metallic stent, would not utilize the method of Ecer to achieve this goal. Clearly, Ecer refers to only locally increasing the hardness, that is at the surface. To support this position, in this response, Applicants submit the §132 Declarations of Dr. Pamela Kramer-Brown, who is not an inventor of the present application. Dr. Kramer-Brown is an employee of Abbott Cardiovascular Systems Inc., the assignee of the present application. Dr. Kramer-Brown works in research and development of stent materials, and particularly, metals. The declarations of Dr. Kramer-Brown supports Applicants' position that one of skill in the art would not have used the method disclosed by Ecer to improve the mechanical properties of a stent.

In sum, one of skill in the art would not have modified the stent of Taylor using the method of Ecer as suggested by the Examiner.

(3) The Combination of Ecer, Taylor, Kraus and Narayanan does not include all claim elements

As noted above, one of skill in the art would not have modified the stent body using the method of Ecer. However, even if one were to have modified the stent body of Taylor utilizing the method of Ecer as proposed by the Examiner with the result being a metallic stent body with carbon implanted at a depth from about 300 to about 2500 angstroms from the surface, the Examiner's further modification does not include all claim elements. The Examiner's has suggested that one of skill in the art would have further modified the combination of Taylor in view of Ecer by incorporating some of the teachings of Kraus and Narayanan. However, even with the additional modifications, "the plasma-polymerized film layer is chemically bonded to the carbon deposit," an element of claim 1, is missing from the combination.

The Examiner has cited Kraus for the purported disclosure of chemical bonding of the polymer film to the metallic stent. The Examiner has misinterpreted the reference. Kraus merely discloses that the polymer coating may be applied using chemical vapor deposition. Kraus does not disclose that the polymer coating is chemically or covalently bonded to the stent surface. Moreover, the disclosure of chemical vapor deposition does not inherently disclose the element. MPEP § 2112 provides the following criteria for a finding of inherency:

> "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Chemical vapor deposition is defined a process described as "the growth of thin solid films on a crystalline substrate as the result of thermochemical vapor-phase reactions" (www.answers.com/topic/chemical-vapor-deposition, from the sci-tech dictionary). There is nothing in the mere disclosure of chemical vapor deposition that necessarily requires that the coating so formed is chemically bonded to the surface. Furthermore, the Examiner has provided no explanation as to how she has arrived at the conclusion that chemical bonding is disclosed. The Examiner has done no more than point to a reference that discloses the formation a polymer coating on a stent by chemical vapor deposition, and then stated, without any further explanation, that chemical bonding would be present.

The Examiner has also cited Narayanan for the plasma polymerization of a polymer coating on the surface of a stent. There is no disclosure in Narayanan that the polymer coating formed chemically bonds to the substrate. Narayanan does disclose that there is covalent bonding between active agents included in the coating and the polymer coating. However, the covalent bonding of active agents to a polymer coating does not suggest or even hint at covalent or chemical bonding of a polymer coating to a metallic substrate.

In summary, there is no disclosure, suggestion, nor hint of chemical bonding of a polymer coating to a substrate in Ecer, Taylor, Kraus, or Narayanan, alone or in combination.

(4) The Examiner has combined the references in an inconsistent manner

As best understood by Applicants, the Examiner has proposed that one would have used the method of Ecer to modify the stent of Taylor to obtain a metallic stent body with implanted carbon, and further modification of the stent by using the polymer coating methods of Kraus and Narayanan. According to the Examiner, if the Taylor stent as modified by Ecer were coated using the method of Kraus, the result would be a polymer coating chemically bonded to the surface of the stent. Then the Examiner turns to Narayanan as disclosing the element "a plasma-polymerized polymer film layer," and thus concludes that one would use the plasma polymerization method of Narayanan to apply the polymer coating of Taylor. In the Examiner's view, Applicants claim 1 is therefore obvious in view of Taylor, Ecer, Kraus and Narayanan.

The Examiner's reasoning is inconsistent. If one were to use the chemical vapor deposition method of Kraus to apply the polymer coating instead of the dipping method of

Taylor to the stent, then in the Examiner's view, a view with which Applicants do not concur, the coating would be "chemically bonded to the surface." However, the coating would not be a "plasma-polymerized polymer film layer." On the other hand, if one were to use the plasma polymerization method of Narayanan instead of the dipping method of Taylor, the coating would meet the "plasma polymerized polymer film layer" element, but it would lack chemical bonding to the substrate.

Thus, as Applicant's best understand the Examiner's position, even without addressing any of the assumptions and conclusions that the Examiner has made, the combination of the four references as proposed by the Examiner does not meet all of the elements of claim 1.

(5) The Examiner is using hindsight

It appears that the Examiner is interpreting a finding of obviousness to require no more than citation to references ostensibly disclosing the individual elements. However, this is not the legal basis for obviousness. According to the Supreme Court,

> a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

*KSR International Co. v. Teleflex Inc. et al.*, 127 S. Ct. 1727, 1741 (2007). It is recognized that this precedent also holds that there need not be a specific teaching, suggestion or motivation in the art. However, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* (citations omitted)(emphasis added).

In the present case, the Examiner has "found" the individual elements in different references, and then used convoluted reasoning to combine them such that the references, at least in the Examiner's opinion, read on Applicants' claim. None of the references disclose chemical bonding of a polymer coating to a stent surface. There is nothing in any of the four references, alone or in combination, that discloses or even hints at the implantation of carbon in the surface

of a stent to increase adhesion of a coating to the surface. The only reference even mentioning implantation of carbon, Ecer, is primarily directed to improving wear and abrasion resistance of metallic parts. It is only with reference to the teaching of Applicants' specification, that is Applicants' teaching of bonding of a layer to carbon deposits in the metallic body, that the Examiner has reached her conclusion. The fact that the Examiner has taken a single sentence from the background of Ecer as the rationale for the combination of Ecer with Taylor, has concluded that chemical bonding occurs based upon the mere recitation of chemical vapor deposition, and has combined the references in an inconsistent manner is evidence that Applicants' claimed invention is not obvious.

## Conclusion

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance. Applicants respectfully request the allowance of pending claims 1, 4 – 6, 8 – 10, 13 and 31.

If necessary to ensure a timely response, this paper should be considered as a petition for an Extension of Time sufficient to provide a timely response. The undersigned authorizes the Commissioner to charge any fees that may be required, or credit of any overpayment to be made, to the **Squire, Sanders, and Dempsey Deposit Account No. 07-1850**.

Should the Examiner have any questions regarding this communication, the Examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

Dated: October 23, 2009

By /Gloria M. Gusler, Reg. No. 50,282/

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# Appendix

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|---|---|
| In re Application of: Shamim M. Malik, et al. | Examiner: Tyson, Melanie Ruano |
| Serial No. 09/997,449 | Art Unit: 3773 |
| Filed: November 30, 2001 | Confirmation No.: 3441 |
| Customer No.: 45159 | Attorney Docket: 050623.00134 |
| Title: A MODIFIED IMPLANTABLE DEVICE SURFACE AND A METHOD OF MAKING THE SAME | |

Mail Stop: **Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

## Declaration under 37 CFR § 1.132

I, Dr. Pamela Kramer-Brown, declare the following:

1. I received a Ph.D. in Materials Science Engineering from the University of California, Berkeley in 1998. I received an M.S. in Materials Science Engineering from the University of California, Berkeley in 1992 and a B.S. in Mechanical Engineering and Materials Science Engineering from the University of California, Berkeley in 1988.

2. I am currently employed by Abbott Vascular, formerly Advanced Cardiovascular Systems, Inc. (ACS), as an Advisor and Technical Manager on metallurgical materials research and development.

3. I was a Principal Engineer and Senior R&D Engineer at ACS from 1998 to 2005. My duties included research and development of stent materials. I was responsible for developing new materials, implementing key technology development methods, and contributing to the creation and revision of ASTM standards critical to the medical device industry.

4. I was a Graduate Researcher at E.O. Lawrence Berkeley National Laboratory from 1989 to 1998. My duties included research on aluminum alloys with discrete surface patterns and Sn/Pb materials containing low gold concentrations.

5. I was a Scientist Associate at Lockheed Missiles and Space Co. in 1989. I performed research on refractory metal alloys, as well as other projects related to materials science.

6. My professional affiliations include ASM International, ASTM, ISMRM, MRS, and TMS.

7. I am not an inventor of the current application, U.S. Patent Application Serial No. 09/997,449.

8. I have read and understand United States Patent No. 4,486,247 to Ecer et al. (Ecer).

9. I understand that Ecer discloses a method of implanting carbon into a steel surface to a depth of about 2500 Angstroms.

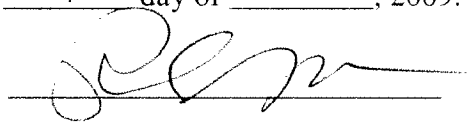
10. I understand that the method disclosed in Ecer is directed to providing "a low friction, high wear resistance surface layer" to improve the wear resistance of the steel.

11. I submit that if I, as a person of skill in the art, were trying to achieve the goal of increasing the tensile strength, stiffness, and resistance to radial compression of a stent, I would not use the carbon implantation method of Ecer on a stainless steel stent body to achieve this goal.

12. I submit that I expect that if the method of Ecer were used on a stainless steel stent body, no significant improvement in the tensile strength, stiffness, and resistance to radial compression of the stent would be observed because the carbon is implanted near the surface of the stent, and would not result in a change in properties in the vast majority of the stent body.

13. I further declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed at **Santa Clara**, California on this 14 day of October, 2009.



Dr. Pamela Kramer-Brown